REMARKS

An Office Action was mailed in the above-captioned application on February 14, 2008. Claims 1, 4, 5, 9-11, 15 and 18-21 were pending in the application. Claims 1, 4, 5, 9-11, 15 and 18-21 were rejected. This Amendment and Remarks document is submitted in response to said Office Action and as the required submission in a Request for Continued Examination.

Interview Summary

An interview was held to discuss this application on Tuesday, May 6, 2008. The participants were SPE Jon Weber, Examiner Afremova, Applicant's representative, Darla G. Yoerg, and in-house counsel Dr. Claude Nassif. Applicant's representatives thank Examiner Afremova and SPE Mr. Weber for the courtesy extended in the interview. All claims were discussed.

Amendment of the claims to overcome the pending rejections was discussed. Namely, agreement was reached that amendment to recite "a condition associated with" in place of "a symptom of" and to recite "injecting" instead of "administering" in claim 1 would overcome the rejections. The conditions associated with prostate cancer have been amended to recite prostatic enlargement, urinary incontinence, urinary retention, and urge-type dysfunction. Cancellation of redundant dependent claims and prosecution of the subject matter of Claim 10 in a continuing application was also discussed.

It was also agreed that a terminal disclaimer over U.S. Patent No. 6,365,164 would be filed.

The Rejection of Claims 1-19 under 35 U.S.C. § 112, second paragraph

The Examiner has rejected Claims 1, 4, 5, 9, 10, 11, 15, and 18-21 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The second paragraph of Section 112 requires that the claims set out and circumscribe a particular area that applicants regard as their invention with a reasonable degree of precision and particularity.

Specifically, the rejection alleges that the claims are drawn to treating prostate cancer due to the recitation of "a patient with prostate cancer" in Claims 1 and 10 but that "alleviating a symptom" is irrelevant to the treatment of prostate cancer because symptoms are not causes of diseases and patients having the symptoms would not necessarily have prostate cancer.

As discussed in the interview of May 6, 2008, the pending claims have been amended to recite a condition associated with prostate cancer. Support for this amendment can be found at page 9, lines 18-25, which states in part, "[a] . . . condition to treat using the methods of the invention are conditions and symptoms associated with prostate cancer or with treatment methods associated with prostate cancer. . . . Symptoms of prostate cancer and conditions associated with prostate cancer may include pain and one or more urological-neurological disorders or symptoms thereof."

By definition, a condition associated with prostate cancer is not prostate cancer. It is therefore possible to alleviate a condition associated with a disease without treating the underlying cause of the disease itself. It is believed that the amendment clarifies that the claims are not directed to treating prostate cancer or treating a cause of prostate cancer, but are limited to the alleviation of specific conditions associated with prostate cancer in a patient with prostate cancer, namely, prostatic enlargement, urinary incontinence, urinary retention, and urge-type dysfunction. The conditions listed in these claims are associated with prostate cancer, as clearly described in the Background section of the specification, and the claims are directed to the alleviation of these conditions in a patient with prostate cancer.

The rejection also states that the claimed invention is indefinite for failing to particularly point out and distinctly claim what is intended by "a therapeutic amount of a botulinum toxin." The specification, at page 8, lines 15-18, defines a therapeutically effective amount of a neurotoxin as "the dosage sufficient to inhibit neuronal activity for at least one week, more preferably one month, most preferably for approximately 6 to 8 months or longer." The

specification also teaches at page 11, lines 17-19 that "[t]herapeutically effective amounts of botulinum toxin can be any amounts or doses that are less than a toxic dose, for example, less than about 3000 IU/70 kg male, preferably between 100 IU/70 kg male to 1200 IU/70 kg." New claims 22-27 have been added and recite exemplary therapeutically effective amount as recited in the specification.

In view of the foregoing amendments and remarks, the Examiner is respectfully requested to reconsider the rejection under 35 U.S.C. § 112, second paragraph.

The Rejection of Claims 1-19 under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 1, 4, 5, 9, 10, 11, 15 and 18-21 under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

The first paragraph of § 112 requires that a patent application be written so as to "enable any person skilled in the art to which it pertains . . . to make and use the same." A specification is presumed to be enabling absent "a reason to doubt the objective truth of the statements contained therein." *In re Marzocchi*, 169 USPQ 367, 369 (C.C.P.A 1971). Further, a specification "may be enabling even though some experimentation is necessary," *United States v. Teletronics, Inc.*, 857 F.2d 778, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), so long as the amount of experimentation required is not "undue experimentation." *In re Wands*, 858 F. 2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The test is whether the specification "provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 858 F. 2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). With this standard in mind, the rejections raised by the Examiner are discussed below.

The claims as amended are directed to a method of alleviating a condition associated with prostate cancer, the method comprising the step of administering a therapeutic amount of botulinum toxin type A into the prostate gland of a patient with prostate cancer, thereby alleviating a condition associated with prostate cancer, wherein the condition associated with prostate cancer is prostatic enlargement, urinary incontinence, urinary retention, and urge-type dysfunction.

The rejection states that "the breadth of the claims is directed to prostate cancer treatment . . . ." The rejection also states that "treatment or cure of prostate cancer" with botulinum toxin is unpredictable. The rejection also states that "the specification does not provide examples of treating prostate cancer or curing prostate cancer." As the claims have been amended to recite alleviation of specific conditions associated with prostate cancer as discussed in the interview, Applicant submits that they are fully enabled.

Example 2 describes shrinkage of prostate volume in rats injected with varying amounts of botulinum toxin, thereby demonstrating botulinum toxin's effects on the prostate. Shrinkage of the prostate is relevant, for example, to the condition of prostatic enlargement.

Applicant submits that these examples are sufficient to enable the claims, which are directed to the alleviation of conditions associated with prostate cancer.

In summary, Applicant has provided a specification that describes the alleviation of symptoms of prostate cancer with botulinum toxin type A through a detailed description of the invention and working examples as detailed here and in the previous response. The description provides a reasonable correlation between the disclosed methods and the claimed subject matter. Applicant therefore submits that the pending claims are fully enabled and respectfully requests reconsideration of the rejection under 35 U.S.C. § 112, first paragraph for lack of enablement.

Double Patenting

As discussed in the interview of May 6, 2008, a terminal disclaimer over U.S. Patent Nos. 6,365,164 is included herewith.

Closing Remarks

Applicant believes that the pending claims are in condition for allowance. Should there be any outstanding issues in this application, the Examiner is invited to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-1970, if not otherwise specifically requested. The

undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-1970.

Respectfully submitted,

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